

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 01 OCT 2001

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Applicant's or agent's file reference 18623-140-1P.	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US00/19774	International filing date (day/month/year) 20 JULY 2000	Priority date (day/month/year) 19 JULY 1999
International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet.		
Applicant EPIMMUNE INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of <u>4</u> sheets. <input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of <u>0</u> sheets.
3. This report contains indications relating to the following items: I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step or industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application

Date of submission of the demand 24 JANUARY 2001	Date of completion of this report 04 SEPTEMBER 2001
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer RON SCHWADRON
Facsimile No. (703) 305-3230	Telephone No. (703) 308-0196

I. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed
- ☒ the description:
pages 1-206, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of
- ☒ the claims:
pages 207-210, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of
- ☒ the drawings:
pages 1-2, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of
- ☒ the sequence listing part of the description:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE
- ☒ the claims, Nos. NONE
- ☒ the drawings, sheets/fig NONE

5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

**Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/19774

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. statement**

Novelty (N)

Claims 2-9,13-29

YES

Claims 1,10-12

NO

Inventive Step (IS)

Claims none

YES

Claims 1-29

NO

Industrial Applicability (IA)

Claims 1-29

YES

Claims NONE

NO

2. citations and explanations (Rule 70.7)

Claims 1,10-12 lack novelty under PCT Article 33(2) as being anticipated by Wentworth et al.

Wentworth et al. teach five of the peptides recited in claim 1 (see Table 2). Wentworth et al. teach a composition of said peptides and APC wherein said APC are dendritic cells which are stimulator cells found in peripheral blood (see page 98, section 2.4). Wentworth et al. teach a composition of said peptide and a pharmaceutically acceptable excipient (see section 2.3).

Claims 1-29 lack an inventive step under PCT Article 33(3) as being obvious over Wentworth et al. in view of Sette et al.

Wentworth et al. teach five of the peptides recited in claim 1 (see Table 2). Wentworth et al. teach a composition of said peptides and APC wherein said APC are dendritic cells which are stimulator cells found in peripheral blood (see page 98, section 2.4). Wentworth teach a composition of said peptide and a pharmaceutically acceptable excipient (see section 2.3). Sette et al. teach pan DR/CTL peptide conjugates (see column 10). Sette et al. teach CTL peptide/lipid conjugates (see column 12). Sette et al. teach multimer or polymers of said peptides (see column 11 and 10). Wentworth teach a CTL peptide of claim 4 (see Table 2). A routineer would have prepared multimers of the peptides disclosed by Wentworth et al. in Table 2 because Sette teach such multimers. The multimers could contain multiple copies of a single peptide disclosed by Wentworth et al. in table 2 or multiple copies of different peptides or multiple copies of both. Sette et al. teach liposomes containing said peptide (see column 14). Sette et al. teach a unit dose of said peptide (see column 15). Sette et al. teach that the peptides are linked via a spacer (see column 12). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed inventions because Wentworth et al. teach the CTL peptides recited in the claims and Sette et al. teach compositions containing CTL peptides and other ingredients and/or multimers containing multiple copies of CTL epitopes.

(Continued on Supplemental Sheet.)

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below:

IPC(7): A61K 38/00, 38/04, 38/08, 38/10, 39/29, 39/295 and US Cl.: 514/2,12,13,14,15, 885; 424/185.1, 189.1

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):

----- NEW CITATIONS -----

NONE

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/19774

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61K 38/00, 38/04, 38/08, 38/10, 39/29, 39/295

US CL : 514/2,12,13,14,15, 885; 424/185.1, 189.1

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 514/2,12,13,14,15, 885; 424/185.1, 189.1

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

MEDLINE, BIOSIS, EMBASE, DERWENT WPI, WEST 2.0, search terms: author names, hcv, peptid?, HLA, htl, ctl,

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim N
Y	WENTWORTH et al. Differences and similarities in the A2.1-restricted cytotoxic T cell repertoire in humans and human leukocyte antigen-transgenic mice. Eur. J. Immunol. 1996. Vol 26. pages 97-101, see entire document.	1-29
Y	US 5,736,142 A (SETTE et al.) 07 April 1998, see entire document.	1-29

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or prior date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Z* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

19 SEPTEMBER 2000

Date of mailing of the international search report

17 OCT 2000

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
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RON SCHWADRON

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NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
 US Department of Commerce
 United States Patent and Trademark
 Office, PCT
 2011 South Clark Place Room
 CP2/5C24
 Arlington, VA 22202
 ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 15 May 2001 (15.05.01)	
International application No. PCT/US00/19774	Applicant's or agent's file reference 18623-140-1P
International filing date (day/month/year) 19 July 2000 (19.07.00)	Priority date (day/month/year) 19 July 1999 (19.07.99)
Applicant SETTE, Alessandro et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
 24 January 2001 (24.01.01)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Kiwa Mpay Telephone No.: (41-22) 338.83.38
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